K062636

JUN - 1 2007

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

Submitter	BIOMET *3i*, Inc. 4555 Riverside Palm Beach Gardens, FL 33410
Contact	Jacquelyn A. Hughes, RAC Director, RA/QA BIOMET *3i*, Inc. 4555 Riverside Palm Beach Gardens, FL 33410 Tel. 561-776-6819 Fax. 561-514-6316 Email jhughes@3implant.com
Date Prepared	May 30, 2007
Device Name	BIOMET *3i* Dental Implants
Classification Name	Endosseous Dental Implants
Device Classification	Class II Dental Devices Panel 21 CFR § 872.3640
Predicate Devices	OSSEOTITE NT Dental Implants – K014235 *3i* Innovation Implants and Cover Screws – K972444 Threaded/Self-Tapping Threaded Implants – K935544 OSSEOTITE Dental implants – K980549 OSSEOTITE Dental Implants – K983347 *3i* Dental Implants – K022009 HA- Coated Endosseous Dental Implants – K955428 *3i* OSSEOTITE NT Certain Implants – K031475 *3i* IOL Implants – K031632 *3i* Implants – K030614 OSSEOTITE NT Certain Implants – K041402 Prevail Implants – K051189 *3i* OSSEOTITE Dental Implants – K051461 NanoTite Dental Implants – K062432

Device Description	BIOMET *3i* Dental Implants are provided with the proprietary OSSEOTITE acid-etched surface, both with and without the additional proprietary NanoTite treatment. Implants are offered in both tapered and parallel-walled/straight designs, and each design provides offerings for either external hex or internal connections. Implants are also offered in various diameters and length.
Indications for Use	BIOMET *3i* dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures. BIOMET *3i* Osseotite and NanoTite dental implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.
Technological Characteristics	The design features and functions are identical to the currently available OSSEOTITE, OSSEOTITE NT, OSSEOTITE Certain, OSSEOTITE Certain NT, Prevail, NanoTite and BIOMET *3i* implants and cover screws.
Performance	Performance standards have not been established by the FDA under Section 514 of the Federal Food, Drug and Cosmetic Act
Performance Testing	Laboratory testing was conducted to determine device functionality and conformance to design input requirements, as well as FDA'S *Class II special controls guidance document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments.* Risk analysis was conducted in accordance with ISO 14971. Results from all of these tests were included in the premarket notification submissions for the predicate device.
Conclusion	BIOMET *3i* Dental Implants are substantially equivalent to the dental implants described in the premarket notification submissions for the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2007

Ms. Jacquelyn A. Hughes, RAC
Director, Regulatory Affairs/Quality Assurance
BIOMET 3*i*, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K062636
Trade/Device Name: BIOMET 3*i* Dental Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: May 3, 2007
Received: May 4, 2007

Dear Ms. Hughes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

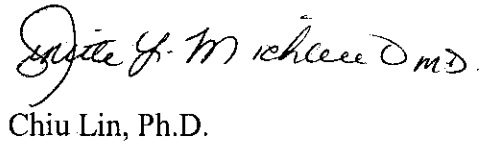
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

BIOMET 3i

Indications for Use Statement

510(k) Number (if known): K062636

Device Name: BIOMET *3i* Dental Implants

Indications for Use:

BIOMET *3i* dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.

BIOMET *3i* Osseotite and NanoTite dental implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mosley for MSR

...ion Sign-Off)

...sion of Anesthesiology, General Hospital,

...ection Control, Dental Devices

...(k) Number: K062636